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| 25944 | 7590 | 10/15/2010 | | | | |
| OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850 | | | | EXAMINER LOVE, TREVOR M | | |
| | | ART UNIT 1611 | PAPER NUMBER ELECTRONIC | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/590,151 | Applicant(s) TAKEDA ET AL. |
| | Examiner TREVOR M. LOVE | Art Unit 1611 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 August 2010.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3,5,8 and 10-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3,5,8 and 10-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 08/09/2010.

Claims 1-3, 5, 8, and 10-12 are pending.

Claim 12 is newly added.

Claims 1 and 11 are currently amended.

Claims 1-3, 5, 8, and 10-12 are currently under consideration.

New Grounds of Rejection - Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed 08/09/2010 has introduced NEW MATTER into the claims.

As presently amended claim 12 recites that the cosmetic is obtained by reacting a mixture consisting of diglycerin with isostearic acid, and then reacting the obtained ester compound with dimer acid. Thus, the claim broadly encompasses compositions wherein only diglycerin and isostearic acid are being mixed, which was not adequately

disclosed by the claims or the specification as originally filed. This is evidenced by the instant specification wherein it is stated that commercially available diglycerines can be utilized, for instance, "Diglycerol", trademark, from Solvay. Solvay Chemicals International (provided with this response) evidences on page 3 that the diglycerol of Solvay has a minimum of 90% diglycerol, and "[t]he remainder of the product is primarily a combination of glycerol and triglycerol". This evidences that pure diglycerol was not utilized, and therefore, the use of "consisting of" language is new matter.

The response did not point out where support for currently amended claim 12 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure.").

As presently amended, the claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the presently amended claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Rejections maintained and Made Again

(note rejection of claim 12 is New Grounds necessitated by Amendment)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 8, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruning et al (U.S. Patent number 6,242,499, Patent issued Jun. 5, 2001).

Gruning teaches a polyglycerol ester that is prepared in two stages. The polyglycerol, which includes diglycerol (diglycerin), is esterified using fatty acid, and then isostearic acid is mixed with the polyglycerol. The composition is heated to 250°C for three hours. The reaction mixture is then cooled to 180°C and is mixed with a dimer acid. The composition is then heated again to 250°C for three hours. An amber-colored viscous product is obtained which is characterized by a hydroxyl number of 68 and an acid number of 1.5 (see column 4, lines 46-62), this reads on **instant claim 5**.

Gruning fails to directly teach the viscosity of the composition. Gruning also fails to directly teach the molar ratios between the components. Furthermore, Gruning fails to directly teach the molecular weight of the composition.

With regard to the viscosity of **instant claim 8**, it is noted that Applicant identifies in the specification, on the paragraph that bridges pages 8 and 9, that by controlling the hydroxyl or acid value "it is possible to easily control the viscosity and the hydroxyl value of the desired hydroxyl compound in the reaction of the ester compound obtained in the first step with a predetermined amount of dimer acid in the second step". It is noted that the hydroxyl value *and* the acid value are similar to the hydroxyl and acid values of example 4 on page 20 of the instant specification. It is noted that the instant specification teaches that it is easy to control the viscosity (see end of paragraph bridging pages 8 and 9 of the specification). It is furthermore noted that Applicant has

shown in table 1 that the instant compositions with the specified viscosities have a hydroxyl value that is between 30 and 80, the composition of Gruning teaches a composition of a hydroxyl value of 68 (see column 4, lines 46-62). Furthermore, the composition is taught as being made by a similar, if the not same method. The instant composition is made by combining the diglycerin and isostearic acid at a temperature of between 180 and 250°C for about 3 to 40 hours, then said dimer is combined with said newly formed ester at a temperature of 150 to 330°C and the acid value of the composition is allowed to be preferably at most 3.0 (see instant specification, page 8, lines 16-30). In Gruning, the polyglycerol and isostearic acid are combined at a temperature of 250°C for 3 hours, then said dimer is combined with said newly formed ester at a temperature of 250°C and the acid value of the composition is 1.5 (see column 4, lines 46-62). Therefore, the viscosity of the composition of Gruning would have been within the claimed ranges since the composition comprises the same components, is reacted in the same way, and has the same hydroxyl and acid values.

With regard to the molar ratios and molecular weight of **instant claims 1-3 and 10**, the exact molecular weight of the polyglycerol component is not directly taught. Gruning teaches that a particularly suitable polyglycerol contains 0-30% glycerol, 15-40% diglycerol, 10-55% triglycerol, 2-25% tetraglycerol, and 0-15% pentaglycerol and higher (see column 3, lines 25-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the molecular weight of the composition, and the molar ratio of the components. One would have been motivated to vary the molar ratio of the components in order to arrive at a desirable amount of

esterification. Furthermore, the molecular weight of the composition depends on the intended use and is readily varied. It is noted the discussion above with regard to claims 6-8 wherein it is identified that both the instant claims and Gruning are teaching a composition with the same components, reacted in the same way, with the same hydroxyl values, and the same acid values, wherein it is also noted that both compositions are being used in cosmetics. It is further noted that MPEP 2144.05 states: "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)."

With regard to the limitation in claim 11, specifically, with the recitation of a "lipstick composition", Applicant is reminded that the intended use of a product claim carries no patentable weight. See MPEP 2111.02. Thus, the intended use of the hydroxyl compound as a lipstick is given no patentable weight.

With regard to the newly added limitation in claim 12, specifically, that the hydroxyl compound is obtained by reacting a mixture consisting of diglycerin with isostearic acid, it is noted that in view of said claim being in the form of product by process, the final product is the only portion of said claim that is limiting. In view of the final product being the same (see above), said limitation is necessarily met.

Response to Arguments and Declaration

Applicant argues in the response filed 08/09/2010 that Gruning fails to provide motivation to modify the polyglycerol component of Grunning. First, it is noted that the claims are broadly drawn to a "hydroxyl compound" having a hydroxyl value in the range of 30 to 80 and a molecular weight of in a range from 2000 to 7000, which is obvious in view of the instantly applied art above. Second, the phrase "obtained by reacting diglycerin with isostearic acid" based on the disclosure and/or definitions provided in the specification is inclusive to other glycerols being present, not just diglycerol, consistent with the teachings of Grunning. Note for instance the use of diglycerol by Solvay (see attached Solvay document), wherein other glycerols are present. In view of the structures being the same, the viscosity would further have necessarily been the same. It is noted that MPEP 2112.01 states: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." Further, Applicant's argument that motivation does not exist is not found persuasive since one would have been motivated to vary the molar ratio of the components in order to arrive at a desirable amount of esterification. Furthermore, the molecular weight of the composition depends on the intended use and

is readily varied. It is noted the discussion above with regard to claims 6-8 wherein it is identified that both the instant claims and Gruning are teaching a composition with the same components, reacted in the same way, with the same hydroxyl values, and the same acid values, wherein it is also noted that both compositions are being used in cosmetics. Specifically, with the final product being the same, one would have been motivated to vary the amounts of the polyglycerol in order to achieve superior esterification. Applicant further argues in the remarks and declaration that the composition of Grunning does not produce the instant invention. Applicant's argument is not found persuasive, and rather, is found curious in view of the composition of Grunning falling within the scope of the claims. The composition of Grunning has the same components and the same hydroxyl value, assuming that the scope of the instant claims is correct, that composition of Grunning is would have the same features such as viscosity and average molecular weight. With regard to Applicant's declaration, the declaration filed 08/09/2010 is not commensurate in scope with the instant invention, particularly in view of the allegation that the teachings of Grunning, which fall within the scope of the instant claims, allegedly does not have features which are imparted by claimed structures. It is noted that MPEP 716.02 (d) states that "[w]hether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ

289, 296 (CCPA 1980) [...] [s]ee also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) [...]; *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983)."

Conclusion

No claims allowed. All claims rejected. No claims objected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643